

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

THE UNITED STATES of AMERICA, et al.,
ex rel. JULIE LONG,

Plaintiffs,

v.

JANSSEN BIOTECH, INC.,

Defendant.

**Civil Action No.
16-12182-FDS**

**MEMORANDUM AND ORDER CONCERNING
RELATOR'S MOTION FOR *IN CAMERA* REVIEW AND
DEFENDANT'S MOTION FOR A PROTECTIVE ORDER**

SAYLOR, C.J.

This is a *qui tam* action alleging that a pharmaceutical company unlawfully provided free services to physicians who prescribed its medications. Relator Julie Long sued defendant Janssen Biotech, Inc., a company that manufactures and sells Remicade and Simponi ARIA, two infusible medications used to treat various conditions. She contends that the services constituted kickbacks in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), which in turn resulted in the payment of false claims in violation of the False Claims Act, 31 U.S.C. § 3729(a).

As part of their ongoing discovery process, the parties have each filed a motion concerning the scope of discoverable material. Relator has moved for an *in camera* review of certain documents withheld or redacted by defendant on the basis of attorney-client privilege. She contends that defendant has not sufficiently demonstrated that the documents at issue, which allegedly relate to defendant's scienter, are privileged.

Defendant has moved for a protective order under Fed. R. Civ. P. 26(c)(1) concerning the deposition notice served by relator pursuant to Fed. R. Civ. P. 30(b)(6). Defendant asserts that certain topics designated by relator either call for the disclosure of privileged information or are unreasonably expansive. Defendant therefore seeks an order prohibiting inquiry into assertedly privileged topics and permitting defendant's corporate designee to answer questions "on a general basis." (Mot. Prot. Order at 11).

For the following reasons, relator's motion for an *in camera* review will be granted, and defendant's motion for a protective order will be denied.

I. Background

Janssen Biotech, Inc. is a wholly-owned subsidiary of Johnson & Johnson.¹ It manufactures and sells pharmaceutical products, including the biopharmaceuticals Remicade and Simponi ARIA. Relator Julie Long was an employee of Janssen from 2003 to February 2016, where she worked as an Area Business Specialist. She was based in Harrisburg, Pennsylvania.

The second amended complaint alleges that Janssen provided free business advisory services to rheumatology and gastroenterology practices that prescribed and infused Remicade and Simponi ARIA. Janssen allegedly employed teams of practice advisers, including relator, and hired outside consultants to provide those services, including presentations, advice, and customized analysis on how to run a profitable in-office infusion ("IOI") business.

According to the complaint, IOI practices derived significant value from those business support services, ranging from the management of a practice's full schedule to advisory consulting that allowed them to increase their profits on many other prescribed medications,

¹ The facts and procedural background are set forth in more detail in the court's Memorandum and Order on Defendant's Motion to Dismiss, filed October 21, 2020. (ECF No. 75).

apart from Remicade or Simponi ARIA. The complaint alleges that by providing those services, Janssen violated the Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b(b), and caused physicians to submit false claims for reimbursement to Medicare and Medicaid in violation of the False Claims Act (“FCA”), 31 U.S.C. § 3729(a).

Relator first filed this suit on October 28, 2016, on behalf of the United States and 28 states. On August 9, 2019, the United States and the various states declined to intervene. On December 13, 2019, the Court ordered the unsealing of the matter.

On October 21, 2020, the Court denied defendant’s motion to dismiss as to the claims brought under the FCA, but granted the motion as to those claims brought under the various state-law analogues to the FCA. On February 15, 2024, the Court denied defendant’s motion for judgment on the pleadings.

Both pending motions involve discovery disputes. The first motion was filed by relator and seeks an *in camera* review of certain documents withheld or redacted by defendant on the basis of attorney-client privilege. The second motion was filed by defendant and seeks a protective order to limit the scope of topics that may be addressed in the Rule 30(b)(6) deposition.

II. Analysis

A. Motion for *In Camera* Review

Relator asks the Court to perform an *in camera* review of documents that she asserts were improperly withheld or redacted by defendant on the basis of attorney-client privilege. She contends that there are reasons to doubt whether the documents at issue are privileged, and that defendant has not provided sufficiently detailed descriptions of the documents to establish that the privilege attaches.

The “burden of showing that documents are privileged rests with the party asserting the

privilege.” See *In re Keeper of the Records (Grand Jury Subpoena Addressed to XYZ Corp.)*, 348 F.3d 16, 21 (1st Cir. 2003). When there is a “legitimate dispute” as to the asserted privilege, the district court may conduct an *in camera* review to determine whether the documents are in fact privileged. See *In re Grand Jury Subpoena (Mr. S.)*, 662 F.3d 65, 70 (1st Cir. 2011) (stating that when “the assertion of privilege is subject to legitimate dispute, the desirability of *in camera* review is heightened”). Indeed, “the very purpose of conducting an *in camera* review is to determine which, if any, of a group of documents are privileged.” *Id.*

Attorney-client privilege attaches “(1) [w]here legal advice of any kind is sought (2) from a professional legal adviser in his capacity as such, (3) the communications relating to that purpose, (4) made in confidence (5) by the client, (6) are at his instance permanently protected (7) from disclosure by himself or by the legal adviser, (8) except the protection be waived.” *Mississippi Pub. Employees’ Ret. Sys. v. Bos. Sci. Corp.*, 649 F.3d 5, 30 (1st Cir. 2011) (quoting *Cavallaro v. United States*, 284 F.3d 236, 245 (1st Cir. 2002)). The privilege “protects ‘only those communications that are confidential and are made for the purpose of seeking or receiving legal advice.’” *Llubes v. Uncommon Prods., LLC*, 663 F.3d 6, 24 (1st Cir. 2011) (quoting *In re Keeper of Records*, 348 F.3d at 22). Although the privilege provides a critical safeguard to encourage disclosures between an attorney and his client, it is nonetheless “narrowly construed because it comes with substantial costs and stands as an obstacle of sorts to the search for truth.” *In re Keeper of Records*, 348 F.3d at 22 (citing *United States v. Nixon*, 418 U.S. 683, 709-10 (1974)).

Here, relator contends that defendant has failed to meet its burden to show that the documents at issue are privileged. Specifically, relator asserts that defendant repeatedly failed to

adequately describe the parties involved in the communications.² According to relator, some communications appear to involve several participants—including multiple employees and third parties—which tends to suggest that the communications are not confidential, and therefore not subject to the privilege. Relator further contends that defendant has asserted the privilege on an inconsistent and overbroad basis throughout the discovery process, including by redacting documents that relator herself created while employed by defendant.

Defendant disputes plaintiff’s characterization of its disclosures. It asserts that it has sufficiently identified the individuals involved in the communications at issue, including those communications involving third parties who, according to defendant, acted as “functional equivalents of [defendant’s] employees.” (Def.’s Opp. at 15).

The Court need not, and indeed cannot, resolve at this stage whether the communications at issue are subject to attorney-client privilege. Rather, as a threshold matter, relator need only demonstrate that there is a “legitimate dispute” as to whether the privilege attaches to the withheld communications. *See In re Grand Jury Subpoena*, 662 F.3d at 70. Because the Court concludes that relator has made a colorable argument disputing the applicability of the privilege to the identified documents, the threshold showing for an *in camera* review has been met.

Nevertheless, the decision whether to conduct such a review “remains within the scope of [the district court’s] discretion[.]” *Id.* In determining whether such a review is appropriate, district courts should consider “the facts and circumstances of the particular case, including, among other things, the volume of materials the district court has been asked to review, the relative importance to the case of the alleged privileged information, and the likelihood that the

² Upon receipt of defendant’s amended privilege log, relator withdrew her request for review of certain communications as to which defendant had failed to identify the specific attorney and client involved. (Reply to Def.’s Opp. at 6).

evidence produced through *in camera* review, together with other available evidence then before the court,” will establish that the documents are privileged. *See United States v. Zolin*, 491 U.S. 554, 572 (1989).

In this case, relator seeks review of approximately 300 files, consisting principally of emails and documents shared between defendant’s employees. Based on relator’s representations, the communications concern defendant’s scienter, an element of the alleged violation. While the Court has substantial reservations about the burden of review, given the number of contested documents, an *in camera* review may resolve the issue and bring discovery to a conclusion.

In short, in order to avoid further discovery delays and attempt to resolve the issue, the Court will conduct an *in camera* review of the contested documents to determine whether privilege has been properly asserted. Relator’s motion will therefore be granted, subject to such further order of the Court as may be appropriate.

To that end, within ten days of this Order (that is, by March 31, 2025), defendant shall provide the Court with (1) copies of the withheld or redacted documents in readily-accessible electronic form, with an index; (2) the most recent version of the privilege log; (3) a list of those persons who were attorneys for defendant and who sent or received the relevant documents; and (4) a list of any persons who sent or received the relevant documents who were not employees of defendant, and as to whom defendant contends there was an attorney-client relationship.

B. Motion for a Protective Order

Defendant has moved for a protective order under Fed. R. Civ. P. 26(c)(1) to set limitations on the scope of topics as to which relator seeks to inquire during a Rule 30(b)(6)

deposition.³

Rule 26(c)(1) provides that “[a] party or any person from whom discovery is sought may move for a protective order in the court where the action is pending.” Fed. R. Civ. P. 26(c)(1). In turn, a court “may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including . . . forbidding inquiry into certain matters, or limiting the scope of disclosure or discovery to certain matters.” *Id.*

Rule 26(c) confers “broad discretion” on the district court “to decide when a protective order is appropriate and what degree of protection is required.” *Poliquin v. Garden Way, Inc.*, 989 F.2d 527, 532 (1st Cir. 1993) (quoting *Seattle Times Co. v. Rhinehart*, 467 U.S. 20, 36, (1984)). Nevertheless, “the party seeking a protective order bears the burden of establishing good cause and a specific need for protection.” *Autoridad de Carreteras y Transportacion v. Transcore Atl., Inc.*, 319 F.R.D. 422, 437 (D.P.R. 2016) (citing *Pub. Citizen v. Liggett Grp., Inc.*, 858 F.2d 775, 779 (1st Cir. 1988)). “A finding of good cause must be based on a particular factual demonstration of potential harm, not on conclusory statements.” *Anderson v. Cryovac, Inc.*, 805 F.2d 1, 7 (1st Cir. 1986).

Defendant first contends that topics 4, 1(p), and 2(l) are privileged. Those topics cover inquiries into (1) defendant’s knowledge and understanding of the prevailing anti-kickback law and regulatory scheme, (2) the actions defendant took to determine whether its programs violated the AKS or FCA, and (3) whether defendant knew or had reason to believe that its actions violated the law. (Mot. Prot. Order at 3).

³ Rule 30(b)(6) governs depositions of organizations. Under the rule, an organization named in a notice or subpoena “must designate one or more officers, directors, or managing agents, or designate other persons to testify on its behalf.” *Cook v. Lynn & William, Inc.*, 344 F.R.D. 149, 153 (D. Mass. 2023) (quoting Fed. R. Civ. P. 30(b)(6)).

A violation of the AKS requires proof that a defendant acted “willfully.” Relator therefore suggests that it is necessary to ask about defendant’s knowledge and understanding that its actions were (or may have been) illegal. (Rel.’s Opp. at 10). Relator does not contend that defendant must disclose any information that it believes to be privileged. Relator further asserts that defendant’s counsel may object to questions during the deposition and instruct the deponent not to answer any question that requires disclosure of privileged information. (*Id.* at 12).

Under the circumstances, a protective order that completely prohibits inquiry into the disputed topics is not appropriate. To the extent that defendant, in good faith, believes that answers to certain questions would require disclosure of privileged information, pursuant to Fed. R. Civ. P. 30(c)(2), counsel may object and instruct the deponent not to answer those questions. Counsel for relator will be expected to make a good-faith effort to refrain from asking questions that would require the disclosure of privileged information. Defendant’s motion concerning the privileged nature of topics 4, 1(p), and 2(l) will therefore be denied.

Next, defendant contends that several topics seek excessively detailed information that is improper for a Rule 30(b)(6) deposition. Specifically, defendant expresses concern about having to address informational requests for 36 distinct clinical programs spanning more than 15 years. Many of those requests, according to defendant, are also unreasonably granular, lack sufficient particularity, or are duplicative in nature. Relator responds by asserting that defendant overstates the level of detail sought and that, properly understood, the deposition topics are proportional to the needs of the case.

Despite engaging in multiple meet-and-confer conferences, the parties appear to be talking past each other to some extent. Relator represents that a subset of contested topics requires nothing more than a “yes” or “no” answer; defendant was apparently unaware of

relator's position, and is "open to withdrawing its objections" if relator's representation is sincere. (Reply to Rel.'s Opp. at 8). In addition, relator represents that it does not seek the minute level of detail that defendant opposes, revealing a further misunderstanding of expectations between the parties. Ultimately, relator must recognize that "[a] corporate designee is 'not expected to be a corporate encyclopedia,' able to answer anything and everything about the company." *One World, LLC v. Manolakos*, 2024 WL 3458347, at *3 (D. Mass. July 18, 2024) (citation omitted). At the same time, defendant must understand that it "has a duty to make a conscientious good-faith effort to prepare [its designee(s)] in order that they can answer fully, completely, and unevasively." *Goguen v. Textron, Inc.*, 2006 WL 8462418, at *4 (D. Mass. Mar. 8, 2006) (internal quotations omitted). A protective order is not appropriate to resolve those gaps in communication.

As for defendant's concern about the breadth of the designated topics, the Court reiterates that the scope of Phase One discovery is limited to the region for which relator was responsible and as to which she has direct personal knowledge—that is, central Pennsylvania—and any regional or national policies or procedures that had a direct bearing on her work. (*See* ECF No. 444). The Rule 30(b)(6) deposition topics may not, at this stage, exceed the bounds of Phase One discovery. With that understanding, the Court does not find that the topics are unnecessarily burdensome or otherwise disproportionate to the needs of the case.

Moreover, defendant's contention that several topics are not sufficiently particularized appears to be unfounded. Rule 30(b)(6) requires the noticing party to describe the topics of examination with "reasonable particularity." Fed. R. Civ. P. 30(b)(6). The identified topics—1, 2(c), 5, 11, 13, 14, 17—meet that standard by specifically focusing on various aspects of defendant's IOI programs, including the process by which the programs were established;

defendant's compliance practices, business model, and strategy; and its corporate organizational structure.⁴ Without question, these topics cover a wide range of information. But the burdensome nature of adequately preparing a Rule 30(b)(6) deposition is "merely the result of the concomitant obligation from the privilege of being able to use the corporate form in order to conduct business." *SiOnyx, LLC v. Hamamatsu Photonics K.K.*, 2017 WL 8236153, at *2 (D. Mass. Oct. 13, 2017). And again, the parties are expected to approach the deposition with a modicum of professionalism and reasonability. The corporate designee must be prepared to answer questions fully, but need not have encyclopedic knowledge of the listed topics, and shall not be subject to questions that concern clinics or operations outside of relator's region in Pennsylvania. *See Manolakos*, 2024 WL 3458347, at *3.

In sum, a protective order is unwarranted, and defendant's motion will be denied, again subject to such further order of the Court as may be appropriate.

III. Conclusion

For the foregoing reasons, relator's Motion for *In Camera* Review (ECF No. 445) is GRANTED, and defendant's Motion for a Protective Order (ECF No. 450) is DENIED.

Within ten days of this Order (that is, by March 31, 2025), defendant shall provide the Court with (1) copies of the withheld or redacted documents in readily-accessible electronic form, with an index; (2) the most recent version of the privilege log; (3) a list of those persons who were attorneys for defendant and who sent or received the relevant documents; and (4) a list of any persons who sent or received the relevant documents who were not employees of defendant, and as to whom defendant contends there was an attorney-client relationship.

⁴ Defendant also contends that topic 2(b) is insufficiently particularized, but relator has withdrawn that topic. (Reply to Def.'s Opp. at 10).

So Ordered.

Dated: March 21, 2025

/s/ F. Dennis Saylor IV
F. Dennis Saylor IV
Chief Judge, United States District Court